REMARKS

The undersigned wishes to thank the Examiner for her time and courtesy extended during the telephonic interview held on February 22, 2012. The following is intended to constitute a proper recordation of such interview in accordance with MPEP 713.04. A common understanding was reached on many elements of the invention and Applicant's representative is grateful for the many helpful suggestions offered by the Examiner. . It was agreed during the interview that arguments and claim amendments could be made to overcome the rejections. The amended claims included with this response reflect the comments and suggestions offered by the Examiner.

Upon entry of this paper, claims 19-68 and 70-83 will be pending in the application. Claims 32-40, 48-57, 66-69, and 74-83 are elected and are presented for consideration. Claims 1-18, and 69 were previously canceled and claims 19-31, 41-47, 58-65, and 70-73 remain withdrawn from consideration. Applicant hereby amends claims 32, 33, 35, 48, 50, 66, 68, and 74. Applicant submits that these claim amendments introduce no new matter to the application. Support for the claim amendments can be found, e.g., at paragraphs [0028], [0033], [0044], [0120], [0131], [0132], [0162], [0167], [0178], [0179], [0183], [0184], of Applicant's Published Application (No. 2009-0014012), and in the claims as originally filed.

Rejection Under 35 U.S.C. § 102(e)

The Office Action rejects claims 32-34, 40, 48-52, 55, 57, 66, 68, 74, and 75 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,961,440 to Schweich, Jr. et al. ("Schweich"). Of these, claims 32, 48, 66, 68, and 74 are independent.

For reference, Applicant attaches to this paper Exhibit A (Flynn et al., *The Use of Drains in Oral and Maxillofacial Surgery: A Review and a New Appraoch*, J. Oral Maxillofac Surg, 41:508-511, 1983) and Exhibit B (U.S. Patent No. 5.437,292 to Kipshidze et al.) that exemplify the knowledge of one of ordinary skill in the art.

Applicant respectfully submits that Schweich fails to disclose each and every element of independent claims 32, 48, 66, 68, and 74. Applicant amends each of these independent claims to recite that the tissue retractor is configured to permit sufficient fluid drainage to prevent

infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. (See, e.g., Applicant's Published Application No. 2009-0014012 at paragraphs [0162] and [0183].) Embodiments of Applicant's invention include a retractor member that "presses on the mucosal surface of the tongue, soft palate, pharyngeal walls, or supraglottic larynx." (Id. at ¶ [0184].) Mucosal linings cover cavities that are exposed to the environment outside the body and include, e.g., the tongue, pharynx, and mouth. It is well-known that a device configured for transmucosal insertion into soft tissue, such as Applicant's device, must allow for fluid drainage from the insertion (e.g., the internal area of the soft tissue that is in contact with the shaft) to prevent infection. (Exhibit A at pages 508 and 509.) This is because the device connects the interior of the body to its exterior, specifically the mouth. The mouth is known to contain great amounts of pathogenic bacteria capable of causing serious life threatening infections. To prevent this, an ongoing seepage of fluid is needed from the internal shaft of the device toward its ends to wash bacteria out. (Exhibit A at page 509.) Without this flow, fluid contaminated with bacteria will incubate and cause an infection along the shaft. (See Exhibit A, Flynn et al., *The Use of Drains in Oral and Maxillofacial Surgery: A Review and a New Appraoch*, J. Oral Maxillofac Surg, 41:508-511, 1983 ("Placement of surgical drains, both intraorally and extraorally, is a common technique of oral and maxillofacial surgery. Drains are used to evacuate pus, pooled blood, or serum from wounds, as well as to eliminate potential dead tissue space. ... Complications of surgical wound drainage include tissue reaction to the drain material, irritation or erosion of adjacent structures, creation of dead space about the drain itself, and most significantly, potentiation of infection in clean wounds. ... Furthermore, the drain may provide a pathway for the migration of surface pathogens into the interior of a wound."))

The tissue retractor of Applicant's claims not only permits sufficient fluid drainage to prevent infection, as is known in the art and is known in the art to be mandatory (see infra), but Applicant's retractor also exerts a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. The balance of these two design elements is difficult. If too much force is applied then the device will not permit sufficient fluid drainage or blood circulation and if too little force is applied then the device will be ineffective as it will not exert a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. "The amount of pressure that an implant can exert without causing damage is largely related to

the pressure at which blood flow is compromised." (Applicant's Published Application No. 2009-0014012 at paragraph [0167].) "For the purpose of retaining the tongue curve the counter pressure is preferably 0.01 to 1000 grams per cm^2, more preferably 0.1 to 100 grams per cm^2, and most preferably 1 to 10 grams per cm^2." (Id.)

Specifically with respect to the tongue, the "muscle is very flexible and easy to deform, however, the converse is also true, and very little force is needed to prevent this deformation." (Id. at paragraph [0028].) "Therefore, if sufficient counterforce is exerted at the proper localized area of the tongue it can prevent obstruction without noticeable effects on speech and swallowing movements." (Id. at paragraphs [0028] and [0044].) This problem was difficult to solve because the tongue "is very mobile during speech and swallowing [and] therefore the amount of force exerted must be low and highly localized." (Id. at paragraphs [0029]-[0030].) "It is unacceptable to render the area immobile, as would be done if [the tongue] were stiffened by a large implant or scar tissue" or if too much force was applied by the device. (Id. at paragraph [0030].)

Applicant submits that Schweich does not anticipate these claims at least because Schweich fails to teach or suggest a tissue retractor that is configured to permit sufficient fluid drainage to prevent infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. Rather, Schweich describes an "apparatus for treatment of a failing heart by reducing the wall tension therein." (Schweich at Abstract.) The "apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane." (Id. at Col. 2, Lines 56-59.) The tension members are "disposed at opposite ends for engagement with the heart or chamber wall." (Id. at Col. 2, Lines 59-61.)

Schweich provides two examples describing the amount of force his device applies. First, "with an original cylindrical radius of four centimeters and a pressure within the chamber of 140 mm of mercury, the wall tension T in the walls of the cylinder is 104.4 newtons." (Id. at Col. 10, Lines 60-65.) "When a 3.84 cm splint is placed as shown in FIGS. 37 and 38 such that l=3.84 cm, the wall tension T is 77.33 newtons." (Id.) Therefore, in this first example, the device of Schweich reduces the wall tension from 104.4 newtons to 77.33 newtons, or a reduction of 27.07 newtons. In the second example of Schweich, "assuming that the chamber

length L is a constant 10cm, the original radium R_1 is 4cm, at a 140 mmHg the tension in the walls is 74.7 N." (Id. at Col. 11, Lines 3-7.) "If "a 4.5 cm splint is placed such that l=4.5 cm, the wall tension will then be 52.8 N." (Id. at Col. 11, lines 3-7.) Therefore, in the second example the device of Schweich reduces the wall tension from 74.7 newtons to 52.8 newtons, or a reduction of 21.9 newtons.

The tension forces described in Schweich, i.e., 77 and 74 newtons, are much higher than the forces described in Applicant's independent claims and specification, such that the device of Schweich is not configured to permit sufficient fluid drainage to prevent infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. The forces described by Applicant, which are sufficient to prevent the deformation of the external surface of the soft tissue or tongue while permitting sufficient fluid drainage are, at the highest, 1000 grams per cm^2 or approximately 10 newtons. The forces described by Schweich are many times higher than the forces described by Applicant. The device of Schweich is not configured to permit sufficient fluid drainage to prevent infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue because the forces applied by the device of Schweich would result in noticeable effects of speech and swallowing movements as well as rendering the area where the device is applied immobile. These are inacceptable outcomes for a device placed in a patients oral cavity or pharynx.

In addition, one skilled in the art knows that the device of Schweich, which has tension members disposed for engagement with the heart wall, must include a mechanism to prevent fluid leakage/seepage (e.g., blood) from the heart, where the device punctures the heart wall. (Exhibit B at Column 1, Lines 6-29.) Specifically, blood within the heart is always at a high pressure and literally squirts out of any puncture. Even minor punctures of the heart cause bleeding that can cause death in minutes. (Id.) Moreover, it is known that high pressure blood will track along any smooth surface to escape. Generally the only approaches to preventing leaking blood in the heart require implantation into heart with growth of tissue into and around the implant. Accordingly, the leak prevention features mandatory in Schweich, if applied to a transmucosal insertion (as recited in Applicant's claims), would result in infection and thus would not be useable for this purpose. (See, Exhibit B, U.S. Patent No. 5.437,292 to Kipshidze et al. ("The present invention is directed to methods for stopping the leakage of blood from

punctures in blood vessels, arterial and venous vessel walls, such as which occur during diagnostic and interventional cardiac and peripheral catheterizations and vascular, endoscopic and orthopedic surgical procedures through induced hemostasis. The control of bleeding during and after surgical procedures is a critical undertaking, especially if the procedure is performed directly upon or involves the patient's arteries and veins."}) Therefore, Schweich is not configured to permit sufficient fluid drainage to prevent infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue, and in fact, the device of Schweich is configured for the opposite function, i.e., to prevent, not permit, fluid drainage.

In view of the foregoing, Applicant respectfully submits that Schweich fails to teach or suggest each and every element of independent claims 32, 48, 66, 68, and 74 at least because Schweich fails to disclose a tissue retractor configured to permit sufficient fluid drainage to prevent infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims under 35 U.S.C. § 102(e) in view of Schweich. Furthermore, Applicant respectfully submits that claims 33-34, 40, 49-52, 55, 57, and 75 are also allowable as each depends from an allowable independent claim.

Rejection Under 35 U.S.C. § 103(a)

The Office Action rejects dependent claims 35, 37, 53, 56, 67, and 76-83 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schweich. As discussed above, Schweich fails to teach or suggest each and every element of amended independent claims 32, 48, 66, 68, and 74 since Schweich does not teach or suggest a tissue retractor configured to permit sufficient fluid drainage to prevent infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. Applicant respectfully submits that claims 35, 37, 53, 56, 67, and 76-83 are allowable as each depends from an allowable independent claim.

The Office Action also rejects dependent claims 36, 38, 39, and 54 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schweich in view of U.S. Patent No. 4,254,774 to Boretos ("Boretos"). As discussed above, Schweich fails to teach or suggest each and every element of independent claims 32, 48, 66, 68, and 74. Applicant submits that Boretos does not cure the defects of Schweich.

Boretos describes the manufacture of catheters with external diameters less than 1 mm and external balloons with walls less than 0.002 inches in thickness. Applicant submits that Boretos does not cure the deficiencies of Schweich in that Boretos, either alone or in combination with Schweich, as Boretos does not teach or suggest a tissue retractor configured to permit sufficient fluid drainage to prevent infection while exerting a force sufficient to prevent the deformation of the external surface of the soft tissue or tongue. Applicant also respectfully submits that claims 36, 38, 39, and 54 are allowable as they depend from allowable independent claims.

Conclusion

Applicant requests that the Examiner reconsider the application and claims in light of the foregoing amendments and remarks, and respectfully submits that the claims are in condition for allowance. The Examiner is invited to call the undersigned at the number below to discuss the application.

Respectfully submitted,

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